HANDOUT FOR STANDADIZATION IN THE FILED OF MEDICAL TEXTILES

STANDARDIZATION

Functions of Division council

- Advise on the subject areas to be taken up for formulation of standards in their respective areas keeping in view the national needs and priorities;
- Set up Sectional Committees within their areas, define their scopes, appoint their Chairmen and members and coordinate their activities;
- Approve proposals for work, decide which proposals should be taken up and direct the Sectional Committee(s) concerned to undertake the approved work and to determine the priority to be assigned to the work.
- Advise on matters relating to research and development needed for the establishment of standards or their revisions;
- Study the work of international organizations and their committees in standards formulation as related to the area of work of the Division Council and recommend on the extent and manner of participation in standardization activities at the international level;
- Advise on implementation of established standards;
- Receive and deal with activity reports and to make recommendations thereon to the Governing Council (GC) concerning matters in which the decision of the GC is necessary;
- Carry out such tasks as may be specifically referred to it by the Governing Council/Standards Advisory Committee.

Sectional Committee

- Sectional committees are appointed by divisional councils or if necessary by the Governing Council for the preparation of a particular standard or group of standards not covered by any division.

- Members from
    - Manufacturers/industry associations
    - Users/consumers
    - NGOs
    - Regulatory & government departments
    - Scientists & technologists
    - Testing organizations
    - Academic institutions

- Consultants

TEXTILES DIVISION COUNCIL

SCOPE: Standardization in the field of textiles and apparel covering natural and man-made fibres and their products, dyestuffs, textile speciality chemicals, textile machinery and technical textiles.

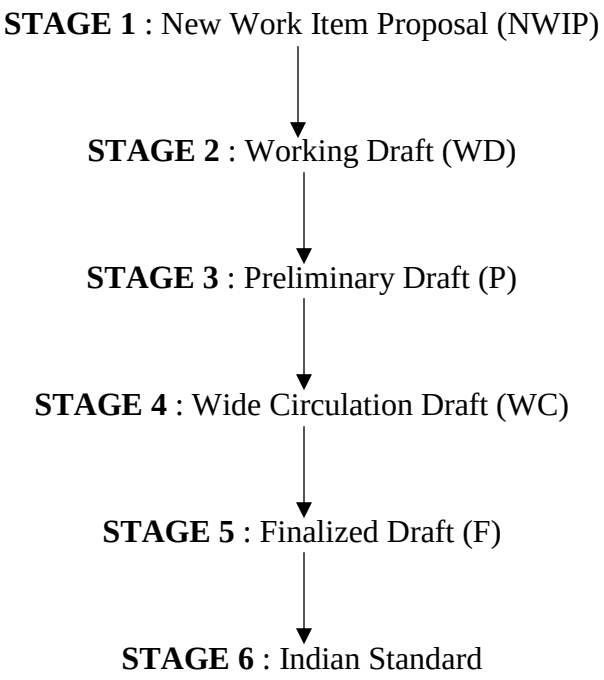
i) Physical Methods of Test Sectional Committee, TXD 01
ii) Jute and Jute Products Sectional Committee, TXD 03
iii) Wool, Wool Products and Textile Floor Coverings Sectional Committee, TXD 04
iv) Chemical Methods of Test Sectional Committee, TXD 05
v) Textiles Speciality Chemicals & Dyestuffs Sectional Committee, TXD 07
vi) Handloom and Khadi Sectional Committee, TXD 08
vii) Cordage Sectional Committee, TXD 09
viii) Hosiery Sectional Committee, TXD 10
ix) Textile Materials for Aeronautical and Related Products Sectional Committee, TXD 13
x) Textile Machinery and Accessories Sectional Committee, TXD 14
xi) Textile Materials for Marine/Fishing Purposes Sectional Committee, TXD 18
xii) Made-up Items (Including Ready-made Garments) Sectional Committee, TXD 20
xiii) Textile Materials Made from Polyolefins (Excluding Cordage) Sectional Committee, TXD 23
xiv) Coir and Coir Products Sectional Committee, TXD 25
xv) Silk and Silk Products Sectional Committee, TXD 28
xvi) Geosynthetics Sectional Committee, TXD 30
xvii) Man-Made Fibres, Cotton and their Products Sectional Committee, TXD 31
xviii) Protective Clothing Sectional Committee, TXD 32
xix) Industrial Fabrics Sectional Committee, TXD 33
xx) Technical Textiles for Buildtech Applications Sectional Committee, TXD 34
xxi) Technical Textiles for Agrotech Applications Sectional Committee, TXD 35
xxii) Technical Textiles for Medtech Applications Sectional Committee, TXD 36
xxiii) Technical Textiles for Sportech Applications Sectional Committee, TXD 37
xxiv) Technical Textiles for Mobiltech Applications Sectional Committee, TXD 38
xxv) Technical Textiles for Clothtech Applications including Narrow Fabrics and Braids Sectional Committee, TXD 39
xxvi) Composites and Speciality Fibres Sectional Committee, TXD 40

TEXTILES DEPARTMENT

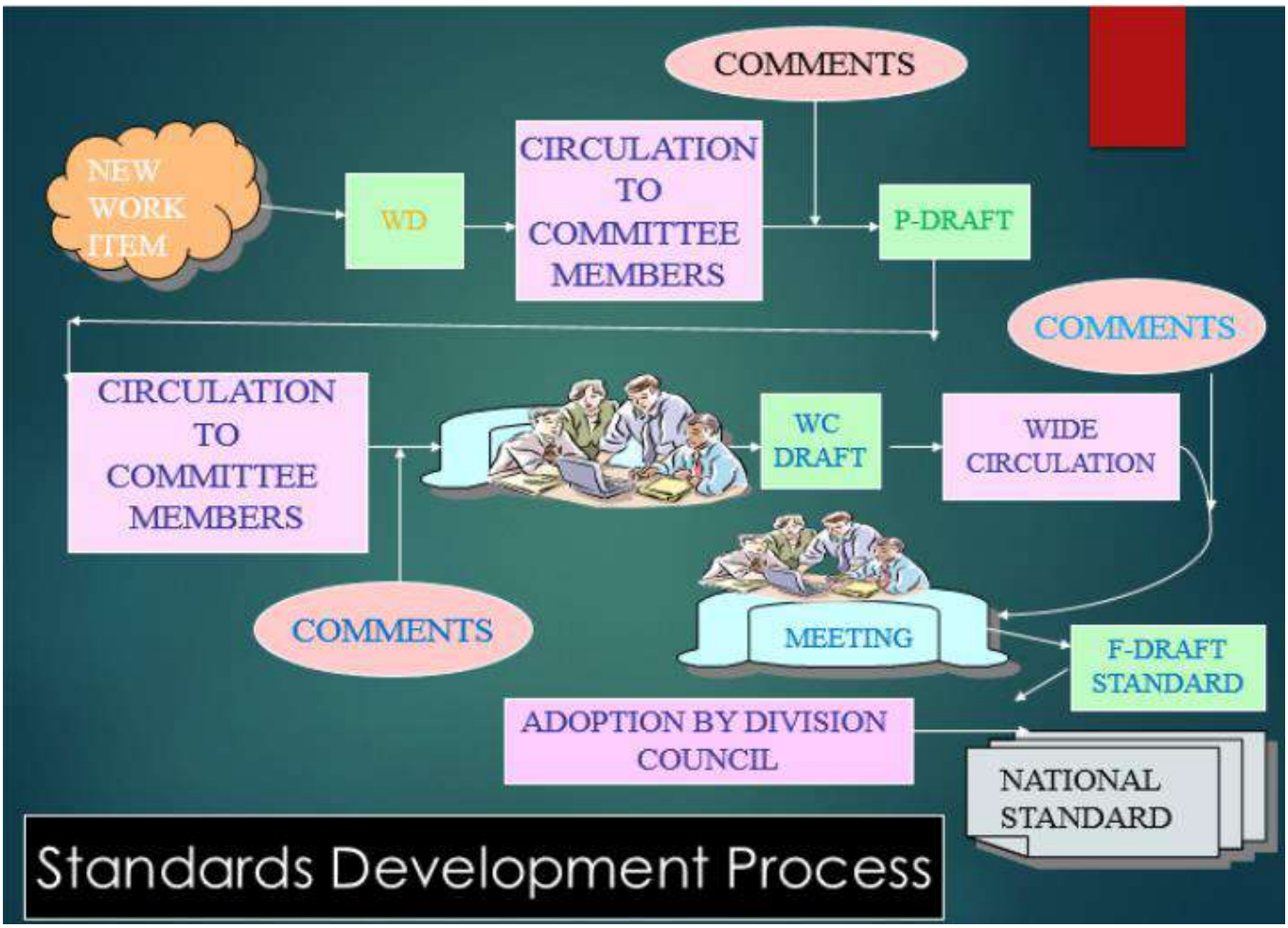
- Around **1400+ standards** for textiles have been published by BIS so far.
- About **400 Indian Standards on technical textiles** including its test methods have been published.

Category wise Summary of standards published by Textiles Division council (TXDC)		
Committee No.	**Sectional Committee Name**	**No. of Standards Published (as on January 2022)**
TXD 01	Physical Methods of Test	109
TXD 03	Jute and Jute Products	36
TXD 04	Wool, Wool Products & Textile Floor Coverings	57
TXD 05	Chemical Methods of Test	184
TXD 07	Textiles Speciality Chemicals & Dyestuffs	65
TXD 08	Handloom & Khadi	87
TXD 09	Cordage	47
TXD 10	Hosiery	41
TXD 13	Textile Materials for Aerospace, Narrow Fabrics and Related Products	29
TXD 14	Textile Machinery and Accessories	188
TXD 18	Textile Materials for Marine/Fishing Purposes	43
TXD 20	Made-up Textiles (Including Ready-made Garments)	28
TXD 23	Textile Materials from Woven Polyolefins	19
TXD 25	Coir and Coir Products	13
TXD 28	Silk and Silk Products	20
TXD 30	Geosynthetics	79
TXD 31	Man-made Fibres, Cotton and their Products	82
TXD 32	Protective Clothing	61
TXD 33	Industrial Fabrics	44
TXD 34	Technical Textiles for Buildtech Applications	7
TXD 35	Technical Textiles for Agrotech Applications	24
TXD 36	Technical Textiles for Medtech Applications	72
TXD 37	Technical Textiles for Sportech Applications	3
TXD 38	Technical Textiles for Mobiltech Applications	17
TXD 39	Technical Textiles for Clothtech Applications	33
TXD 40	Composites and Speciality Fibres	33
		1421

Process of Standards Development at National Level



Stage 2 to 3 : Building consensus among panel/committee members
Stage 3 to 5 : Building national consensus



IMPORTANCE OF STANDARDS

- Facilitate safety, security, interoperability, traceability, quality and continual improvement of goods and services
- Protection of health and environment
- Basis for technical regulations and contracts
- Technology Transfer and Knowledge sharing
- Impact the economy of the country
- Trade balances, Growth, Productivity

NEW INITIATIVE BY BIS

a) Digitalization of Standardization activity (Circulation of agenda, minutes, meeting notice, communications, comments on published standards, Proposal for new subject, Comments on WC drafts on Manakonline only)

b) Capacity building by providing training to Committee members on Standardization
c) Provision of an additional alternate members up to the age of 37 years to enable participation of Young Professional in Standardization work and for proper succession plan.
d) FREE ACCESS TO INDIAN STANDARD- Indigenous standards made freely accessible and downloadable
e) CREATION OF STANDARDIZATION CELLS at Ministry and Industry associations- Enhance stakeholder involvement in standardization
f) REVIEW OF STANDARDS- Process redesigned
g) ONE NATION ONE STANDARD- Scheme for recognition of SDOs launched
h) MoUs WITH EMINENT INSTITUTES- IITs (Delhi, Bombay, Madras, Kanpur, Roorkee), IIMs(Trichy, Lucknow), HBTU Kanpur, NITRA, NLU

What is Medical Textiles or Medtech?

The Textile Institute (UK) defines medical textiles as “a general term which describes a textile structure which has been designed and produced for use in any of a variety of medical applications, including implantable applications”.
Medical textiles are a major growth area within the scope of technical textiles, which is defined as “textile materials and products manufactured primarily for their technical performance and functional properties rather than their aesthetic or decoration characteristics”.

Medtech Sector at a Glance

Out of total Indian textile industry, only 13% contributes to technical textiles, and out of this 13%, the share of Medtech, in technical textiles market is in the range of 6-8%.
The main volume growth driver in Medtech is the Non-implantable segment which includes surgicals & healthcare/hygiene products.
Lack of basic infrastructure in terms of testing facilities, Skilled manpower, Research & Developement, and awareness among users are hindering the growth rate of Indian Medtech industry.

Characteristics of Materials for Medical Use

The major requirements for biomedical materials are as follows:

i) Non toxicity
ii) Non-allergenic response
iii) The ability to be sterilized
iv) Mechanical properties
v) Strength
vi) Elasticity

vii) Durability

viii) Biocompatibility

ix) As biomedical materials may be contaminated with bacteria, sterilization is important for biomedical polymers. The sterilization technique can be physical or chemical.

Fibres Used for Medical and Healthcare Application

Textiles materials that are used in medical applications include fibres, yarns, fabrics and composites. Depending upon the application, the major requirements of medical textiles are absorbency, tenacity, flexibility, softness and at times biostability or biodegradability.

Fibres used in medical field may vary from natural fibre such as cotton, silk, regenerated wood fluff (absorbent layer), to, manmade fibres like polyester, polyamide, polyethylene, glass etc.

The various applications of different fibre in medical field are shown as follows:

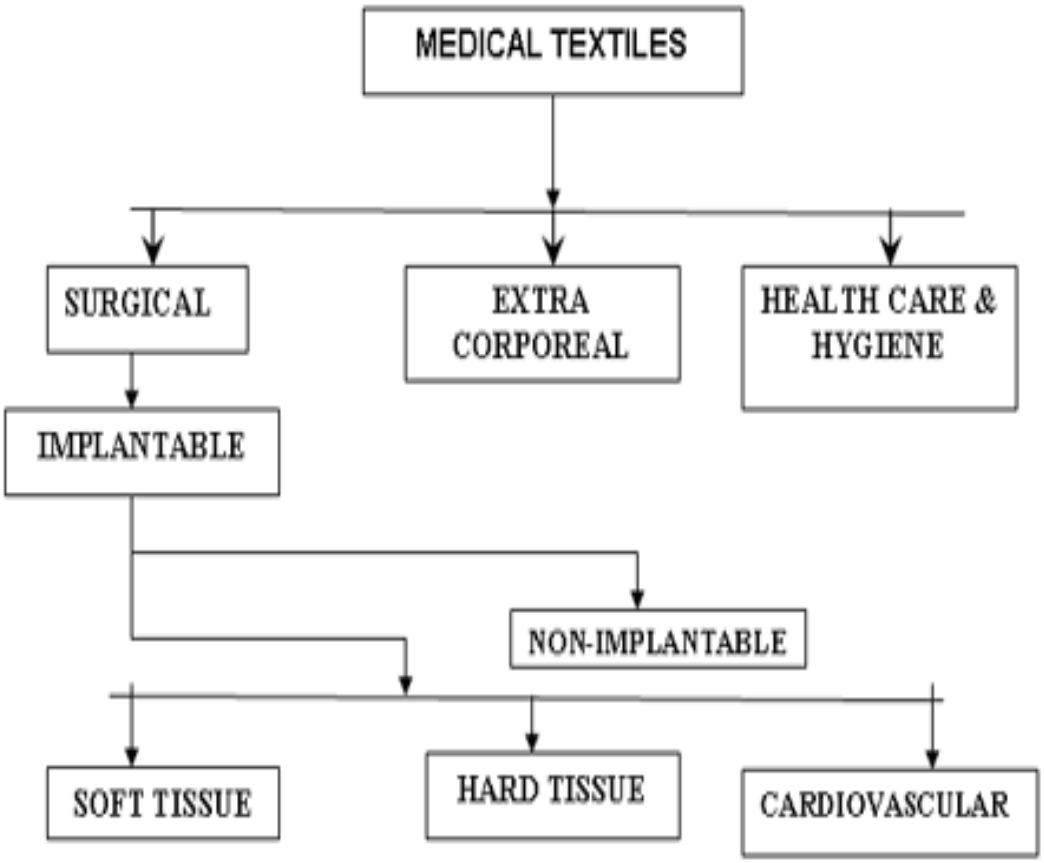
Sl No.	*Fibre*	*Application in medical field*
1	Cotton	Surgical clothing gowns, Beddings, Sheets, Pillow cover, Uniforms, Surgical hosiery
2	Viscose	Caps, Masks, Wipes
3	Polyester	Gowns, Masks, Surgical cover/drapes, Blankets, Coverstock
4	Polyamide	Surgical hosiery
5	Polypropylene	Protective clothing (PPE kits)
6	Polyethylene	Surgical covers, Drapes
7	Glass	Caps, mask
8	Elastomeric	Surgical hosiery

Classification of Medical Textiles

Depending upon the usage, they are classified as:

a) Healthcare and Hygiene products
b) Extracorporeal devices
c) Implantable materials
d) Non-implantable materials

Medical textiles can be classified as follows:



Classification of Medical Textiles

1. Implantable Materials: There is a special type of textile structure that is used for various purposes inside the human body. The use of implantable material can be observed in closure or replacement surgery. For example: Satures, Soft tissue implants, Orthopedic implants, cardiovascular implants, etc. are used in textiles.

Product Applications: Artificial Tendon, Artificial Ligament, Artificial Skin, Artificial Bone, Artificial Cornea, Vascular Grafts, Heart Valves etc.

2. Non-Implantable Materials: Non-implantable medical textiles are used for external application of the body i.e. it is used to help in the recovery of various wounds on the outer part of the body. These textile materials must be non-toxic and resistant to allergens and cancer-causing influencers.

Product Applications: Absorbent Pads, Wound Contact Layers, Bandages, Plasters, Gauze Pads, Lint, Wound Dressing etc.

3. Extra Corporal Devices: Such devices are widely used in modern medical science. This modern textile material is used to replace various organs inside the body of infected people. These devices must have non-toxic, non-carcinogenic, bio-compatibility properties.

Product Applications: Artificial Kidney, Artificial Lung, Artificial Liver etc.

4. Health Care & Hygienic Products: An important area of medical textile is healthcare and hygiene assurance. These textile materials are used to protect physicians and health workers and to equip wards when treating patients in the hospital and will have non-toxic, non-carcinogenic etc. properties.

Product applications: **Surgical masks**, PPE, caps, gowns, bed sheets, curtains, **protective clothing**, baby diapers, sanitary napkins, etc.

STANDARDIZATION IN THE FIELD OF MEDICAL TEXTILES

- Standardization in the field of Medical Textiles has been undertaken by Technical Textiles for Medtech Application Sectional Committee, TXD 36 under Textiles Division Council at BIS:

- Scope of TXD 36 : To formulate Indian Standards for terminology, testing and specifications for technical textiles for medtech applications such as healthcare and hygiene textile products, implantable and non-implantable and extra corporeal textile products.

- Number of standards formulated: 72
- Number of standards under development: 03
- Product Standards: 60
- Method of Tests: 12

IMPORTANT PRODUCT OF MEDICAL TEXTILES

SURGICAL FACE MASK

COVERALL

WIPES

BABY DIAPER

SANITARY NAPKIN

STANDARDIZATION IN THE FIELD OF MEDICAL TEXTILES

IS 16289 : 2014 'MEDICAL TEXTILES — SURGICAL FACE MASKS — SPECIFICATION'

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example noses and mouths of the surgical team. The main intended use of surgical masks is to protect the patients from infective agents from the noses and mouths of the staff and, in certain situations, additionally to protect the wearer against splashes of potentially contaminated liquids.

Surgical masks are very important to protect the patients and medical professional from infective agents during surgical procedures in operating theatres and other medical settings.
This standard specifies the performance requirements and test methods of surgical face masks intended to limit the transmission of infective agents from staff to patients and (in certain situations) vice-versa during surgical procedures in operating theatres and other healthcare services such as patient care, with similar requirements.

Design: The surgical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

The surgical masks have been categorized into three classes based on performance, i.e. Class 1, Class 2 and Class 3.

The key performance requirements specified in IS 16289 Surgical Facemask include Bacterial filtration efficiency and Sub-micron particulate filtration efficiency at 0.1 micron for safety, Differential pressure for comfort, splash resistance to protect from blood and body fluids during surgery.

▶ PERFORMANCE REQUIREMENT FOR SURGICAL FACE MASK

Sl. No.	Characteristic	Requirements		
		Class 1	Class 2	Class 3
i)	Bacterial Filtering Efficiency, Min	95	98	98
ii)	Differential Pressure, Pa, Max	29.4	29.4	49.0
iii)	Splash resistance, mm Hg Min	-	-	120
iv)	Sub-micron particulate filtration Efficiency at 0.1 µ, Percent, Min	-	-	99

IS 17423 : 2021, Medical Textiles — Bio-Protective Coveralls — Specification

(First Revision)

Coverall is a type of personal protective equipment (PPE) intended to be worn by healthcare personnel for the purpose of isolating all parts of the body from a potential hazard. The bio-protective coveralls provide protection against various biological agents due to their material sealing arrangements.

This standard specifies the requirements for single use and reusable bio-protective coveralls intended for medical use.

The fabric used for the manufacturing of coverall shall be a single or multi-layered textile structure made of woven or non-woven (spunlace or spunbond or combination of spunbond and meltblown) or knitted structure with or without coating / lamination engineered to fulfil the functional requirements. The bio-protective coveralls consists of an integrated hood with elastic around face opening. It shall be provided with suitable fastening arrangement which shall be covered with a storm flap provided with suitable self-adhesive sealing arrangement such as a double-sided tape etc.

Coverall may also be provided with elastic wrists and ankles for convenience and freedom for movement. It shall also be provided with thumb loop for better and secure fit during overhead work. The seams shall be sealed with a tape of suitable material of medical grade of minimum 16 mm width or any other sealing arrangement. Each coverall shall be provided with a pair of shoe covers with an elastic strip to tighten it with the coverall, so that there is no passage for air through it.

▶ **Depending upon the end use the Bio-protective coveralls have been classified into four performance levels (level 1 to level 4)**

Requirements	Level 1	Level 2	Level 3	Level 4	Test method
Synthetic blood penetration resistance	up to 1.75 kPa	up to 3.5 kPa	up to 7 kPa	up to 14 kPa	IS 16546/ISO 16603
Resistance to viral penetration	NA	NA	up to 3.5 kPa	up to 7 kPa	IS 16545/ISO 16604
Breathability (water vapour transmission rate), g/m^2/day, *Min*	1200	1200	800	800	Annex F of IS 16390
Tensile strength (dry and wet), N	≥ 20	≥ 20	≥ 40	≥ 40	Non woven IS 15891-3, Woven IS 1969 (Part 1)
Seam strength (dry and wet) (N)	≥ 20	≥ 20	≥ 32	≥ 32	Nonwoven: IS 15891 (Part18), Woven: IS/ISO 13935 (Part 1)
Bursting strength (dry & wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)

Cleanliness – microbial (CFU/100 cm^2)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737 (Part 1)
Resistance to dry microbial penetration ,(log cfu)	NA	NA	≤ 1	≤ 1	IS 16548/ISO 22612

Physical Significance of requirements for Bio-protective coveralls

1. Synthetic Blood Penetration Resistance: This test method is required to simulate the actual conditions of blood splash observed by the healthcare personnel, when splashes of blood falls (projectile) onto the surface of coverall.

2. Resistance to Viral Penetration: Bacteriophage Phi-X-174 has been used because of its structural properties are quite similar to virus structure. The fabric of the coverall is subject to bacteriophage under certain pressure and performance of the fabric is observed, whether the bacteriophage has passed the fabric or not.

3. Breathability (water vapour transmission rate): This test method is practiced to simulate the comfort or to determine the wearability of the fabric. The amount of water vapours transmitted over the surface of coverall fabric is detected.

4. Mechanical and physical properties like **Tensile strength, Bursting strength and Seam strength** in both dry and wet conditions need to be tested in order to ensure the life of the product or to withstand severe loads and pulls during the procedures.

5. Cleanliness–microbial: In order to get assured for the cleanliness of the product from various microbes, bioburden evaluation is done. The total no. of colony forming units in CFU/100 cm^2 is determined and shall be less than or equal to 300 CFU/100 cm^2.

IS 17334 : 2019 SURGICAL GOWNS AND SURGICAL DRAPES

Surgical Gown — Protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate matter.

Surgical Drape — A covering for the patient for the prevention of transfer of infective agents, such as microorganisms, body fluids and particulate material. "Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings".

Surgical gowns and surgical drapes are intended to be used to minimize the transmission of infective agents between patients and clinical staff during the surgical and other invasive procedures. This standard addresses the performance of surgical gowns and surgical drapes designed to protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures.

Depending upon the various end uses, surgical gowns and surgical drapes have been categorized into four levels (Level 0, level 1, level 2 and level 3). The final performance requirement level shall be based on the performance of the critical zone component. The information for principle of critical area has been specified in the standard.

The following important performance requirements have been covered in this standard for surgical gowns and drapes:

- **Impact penetration** (g)
- **Hydrostatic resistance** (cmwc)
- **Blood resistance** and **viral resistance**
- **Particle release**
- **Tensile strength** and **bursting strength** (dry and wet)
- **Resistance to microbial penetration** – dry and wet
- **Biocompatibility** evaluation (cytotoxicity and irritation sensitization)
- To ensure the **comfort**, requirement for **moisture vapour transmission rate** has also been specified for **level 3 gowns**

a) Name of the product;

appropriate, the method of re-sterilization and

Table 1 Performance Requirements for Surgical Gowns

(*Clauses* 5.1, 6.2, 8.1.1, 8.2.2 *and* 9.1)

Sl No.	Characteristics	Requirement				Method of Test, Ref to
		Level 0	Level 1	Level 2	Level 3	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i)	Impact penetration (g)	< 4.5	NA	NA	NA	ISO 18695
ii)	Hydrostatic resistance (cmwc)	NA	≥ 20	≥ 50	NA	ISO 811
iii)	Blood resistance	NA	NA	NA	Pass	IS 16546
iv)	Viral resistance	—	—	—	Pass	IS 16545
v)	Particle release [log10 (lint count)]	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	IS 15891 (Part 10)
vi)	Tensile strength (dry and wet) (N)	≥ 20	≥ 20	≥ 20	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
vii)	Bursting strength (dry and wet) (kPa)	≥ 40	≥ 40	≥ 40	≥ 40	IS 1966 (Part 1)
viii)	Cleanliness–microbial (CFU/100 cm^2)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
ix)	Resistance to microbial penetration — Dry (CFU)	NA	≤ 300	≤ 300 (for less critical zones)	NA	IS 16548
x)	Resistance to microbial penetration — Wet (I_a)	NA	NA	6.0 (for critical zones)	—	IS 16549
xi)	*Biocompatibility Evaluation — Cytotoxicity	None	None	None	None	IS/ISO 10993-5
	*Biocompatibility Evaluation — Irritation and skin sensitization	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	Non-irritant and non-sensitizer	IS/ISO 10993-10
xii)	Moisture vapour transmission rate (*Max.*) (optional)	NA	NA	NA	40 m^2 Pa/W	ISO 11092

*Remarks : Confirm the biocompatibility of raw material at designed stage for all levels. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

IS 5405 : 2019, SANITARY NAPKINS

Sanitary napkin is an absorbent material used to absorb fluid discharged during menstruation. As compared to cloth and other materials (husks, ashes, etc.) used during menstruation, it provides better hygiene and protection against leakage.

This standard covers the requirements for disposable (non-reusable) sanitary napkins for external use. All types of sanitary napkins basically consist of three major components:

a) cover or the top sheet;

b) absorbent core, and

c) the barrier or bottom sheet.

PERFORMANCE REQUIREMENT OF SANITARY PAD

- *p*H : 5.5 – 8.0
- Ability to withstand pressure after absorption : No leakage after absorption of 30 ml coloured distilled water.
- Bacterial and Fungal Bioburden : Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm
- Test for Common Skin Pathogen — Staphylococcus Aureus : Shall be absent
- Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization : The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively.
- Optional requirement for Biodegradability and Compostability.
- Good manufacturing practice guidelines for hygiene requirement have been specified in the standard.

IS 17514 : 2021, REUSABLE SANITARY PAD/ SANITARY NAPKIN / PERIOD PANTIES

Reusable sanitary pad/sanitary napkin/period panties are hygiene products that are worn by menstruators (children and adults) to absorb blood and other fluids during menstrual periods.
This standard covers the requirements for reusable (multiple use) sanitary pad/sanitary napkin/period panties for external use.

The raw material/fabric used for manufacturing the product shall meet the following requirements (initially and after declared cycle washes)

Table 1 Colourfastness and Dimensional Stability Requirement of Raw Material/Fabric

(*Clauses* 8 *and* 11.2.4)

Sl No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colour fastness to rubbing		IS/ISO 105-X12
	a) Dry	4 or better	
	b) Wet	3 or better	
ii)	Colour fastness to perspiration (acidic and alkaline)		
	a) Colour change	4 or better	IS/ISO 105-E04
	b) Staining	4 or better	
iii)	Colour fastness to washing		
	a) Colour change	4 or better	IS/ISO 105-C06
	b) Staining	4 or better	
iv)	Dimensional stability to washing, percentage, *Max*		Annex C of IS 16394
	Length and width	± 5	

PERFORMANCE REQUIREMENT OF REUSABLE SANITARY PAD/ SANITARY NAPKIN / PERIOD PANTIES

- *p*H : 5.5 – 8.0
- Ability to withstand pressure after absorption : No leakage after absorption of 10 ml coloured distilled water.
- Bacterial and Fungal Bioburden : Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/gm
- Test for Common Skin Pathogen — Staphylococcus Aureus : Shall be absent
- Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization : The material shall be ‘Non-reactive, Non-irritant and Non-sensitizer’ respectively.

- Anti-bacterial value (before and after declared wash cycles : Shall be greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743

- Good manufacturing practice guidelines for hygiene requirement have been specified in the standard.

IS 17509 : 2021, DISPOSABLE BABY DIAPER — SPECIFICATION

Baby diapers are personal hygiene products that allows the baby to defecate or urinate without the use of a toilet, by absorbing or containing waste products to prevent soiling of outer clothing or the external environment.

This standard covers the requirements for disposable (non-reusable) baby diaper for external use. This standard also covers the types and sizes and requirement for fastening and securing

mechanism of the baby diaper. On the basis of the weight of infant and/or toddler the baby diapers are classified into new born, small, medium, large, extra-large.

	Size	Number of Gushes	Requirement
Minimum Absorption Capacity	New Born	3	3 x 20 ml
	Small	3	3 x 35 ml
	Medium	3	3 x 50 ml
	Large	3	3 x 60 ml
	X Large	3	3 x 70 ml
Rate of absorption per gush (s), Max	All sizes	-	60
Rewet under load, (g), Max	All sizes	-	5

FASTENING AND SECURING MECHANISM

- Baby diaper shall have a suitable device (e.g. mechanical or adhesive) to ensure a good fit of the diaper at the waist and around the legs. The material used shall be safe under normal conditions of use and shall not provide a physical hazard.
- There shall be a device e.g. elastic band or elastic threads on both sides of the absorbentcore that are suitably stretched and fixed between top sheet and back sheet or fixed on topsheet or back sheet to keep the diaper fit on the user's waist and legs and prevent leakage of liquid.
- The adhesive used shall keep the diaper component together and shall not allow shifting of absorbent core or top sheet. The adhesive material used shall not be harmful to the skin of the baby.

PERFORMANCE REQUIREMENTS

- ***p*H Value -** 5.5 to 8.0 when tested by the method given in IS 1390.

- **Rate of Absorption, Rewet under Load and Minimum Absorption Capacity**

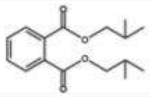
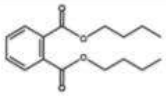
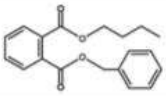
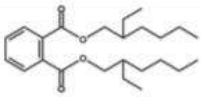
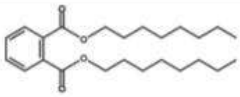
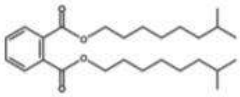
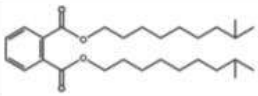
- **Hygiene Testing Requirement**
- Total viable count (total number of bacteria and fungi) shall not be more than 1 000 cfu/g and *Staphylococcus aureus* shall be absent.

- **Phthalate Test** - The amount of phthalate present in baby diaper shall be < 0.1 percent (individual or in combination) when tested as per the method given in IS 9873 (Part 6).

  The test specimen is extracted through a Soxhlet extractor, solvent extractor or ultrasonic bath with dichloromethane. Phthalate esters in the extract are determined qualitatively and quantitatively by gas chromatography-mass spectrometry (GC-MS).

  IS 9873 (Part 6) is method for the determination of di-iso-butyl phthalate (DIBP), di-n-butyl phthalate (DBP), benzylbutyl phthalate (BBP), bis-(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DNOP), di-iso-nonylphthalate (DINP) and di-iso-decyl phthalate (DIDP) in toys and children's products.

Table A.1 — Phthalate esters

No.	Phthalate esters (initialism)	CAS No.	Structure formula[a]	Molecular formula
1	Di-*iso*-butyl phthalate (DIBP)	84–69–5		$C_{16}H_{22}O_4$
2	Di-*n*-butyl phthalate (DBP)	84–74–2		$C_{16}H_{22}O_4$
3	Benzyl butyl phthalate (BBP)	85–68–7		$C_{19}H_{20}O_4$
4	*Bis*-(2-ethylhexyl) phthalate (DEHP)	117–81–7		$C_{24}H_{38}O_4$
5	Di-*n*-octyl phthalate (DNOP)	117–84–0		$C_{24}H_{38}O_4$
6	Di-*iso*-nonyl phthalate (DINP)	28553–12–0[b] 68515–48–0[c]		$C_{26}H_{42}O_4$
7	Di-*iso*-decyl phthalate (DIDP)	26761–40–0[d] 68515–49–1[e]		$C_{28}H_{46}O_4$

- **Biocompatibility Evaluation** — Cytotoxicity, Irritation and Skin Sensitization
- The material shall be 'Non-reactive, Non-irritant and Non-sensitizer' respectively
- **Biodegradability and Compostability (Optional) -** The product shall be biodegradable or compostable when tested as per IS/ISO 17088.
- **Anti-Bacterial Activity Value (Optional)** – Baby diaper shall have antibacterial activity value greater than or equal to 2 when tested by the absorption method prescribed in IS/ISO 20743.

IS 4605 : 2020, CREPE BANDAGE — SPECIFICATION (SECOND REVISION)

Crepe bandage consists of characteristic fabric of plain weave or needle loom weave, in which the warp threads are crepe-twisted for ensuring maximum elasticity. Crepe bandage is used for

dressing of varicose veins, weak ankles, legs, knees and wrists in case of sprains and other conditions in which light support is required.

This standard covers requirements pertaining to material, construction and performance of crepe bandage.

PERFORMANCE REQUIREMENTS

- Material - Cotton or mixture of rayon and cotton shall be used in the manufacture of crepe bandage.
- Threads per Stated Length - Ends: Not less than 170 per dm.
- Picks: Not less than 78 per dm, determined on the fully stretched bandage.
- Weight per Unit Area - The weight of the bandage in fully stretched conditions shall be not less than 160 g/m^2.
- Elasticity - The regain length shall not be more than 80 percent of the fully stretched length
- pH value - 6 to 8.5
- Breaking Load - minimum 150 N (15 kgf) on a test specimen of 20 cm test length and not greater than 5 cm in width
- The water-soluble and ether soluble substances shall not be more than 1 percent respectively.

IS 17629: 2021, MEDICAL TEXTILES — CAPS — SPECIFICATION

Caps are worn as personnel protective clothing for head covering by surgeon, operating room staff and other healthcare professional. Caps are helpful to prevent contamination of the operating field, patient and materials from microorganisms/particulates that originate in the personnel's hair or scalps.

This standard specifies the requirements for caps intended to be worn by surgeon, operating room staff and other healthcare professional during the surgical and other invasive procedures to prevent contamination of the operating field, patient and materials from transfer of hair, microorganisms, particulates etc. They can be single use or re-useable. These caps are also known by other nomenclature, such as operation theatre cap, surgeon cap, surgeon hood, head cover, bouffant cap, nurse cap etc.

PERFORMANCE REQUIREMENT OF CAP

Sl No.	Characteristics	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Cleanliness – Microbial (CFU/100 cm^2)	≤ 300	ISO 11737-1
ii)	Tensile strength (Dry and wet) (N)	≥ 20	Nonwoven, IS 15891 (Part 3), Woven, IS 1969 (Part 1)
iii)	Bursting strength (Dry and wet) (kPa)	≥ 40	IS 1966 (Part 1)
iv)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
v)	Resistance to microbial penetration — Dry (CFU)	≤ 300	IS 16548
vi)	Moisture vapour transmission rate (*Max.*) (*optional*) (*see note*)	40 m^2 Pa/W	IS 17376

NOTE — Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for caps that are being used in high risk surgeries with prolonged duration where the doctors/healthcare personnel are subjected to heat stress due to which they may feel uncomfortable.

IS 17788 : 2021, MEDICAL TEXTILES — NONWOVEN FABRIC FOR WIPES — SPECIFICATION

This standard specifies minimum performance requirements for non-woven fabric for single use dry or wet wipes for baby care and personal hygiene (baby, adult, facial, skin etc).

The key performance requirements specified in the standards are fibre identification, GSM, Absorption, ph, Dry and wet breaking strength.

IS 17787 : 2021, MEDICAL TEXTILES — NONWOVEN WIPES — SPECIFICATION

This standard specifies minimum performance requirements for single use nonwoven dry or wet wipes used for baby care and personal hygiene (baby, adult, facial, skin etc). The key performance requirements specified in the standards are length and width, ph, seal leakage test, Total viable count, microbiological requirements, antibacterial activity.

Standards published by Technical Textiles for Medtech applications Sectional Committee, TXD 36

SI. No.	IS No.	TITLE
1.	IS 674 : 1987	Specification for flannel, hospital, grey (third revision)
2.	IS 757 : 1971	Specification for handloom cotton lint, absorbent, bleached, non-sterilized (first revision)
3.	IS 758 : 1988	Specification for cotton gauze, absorbent, non-sterilized (fourth revision)
4.	IS 863 : 1988	Specification for cotton bandage cloth, non-sterilized (second revision)
5.	IS 1681 : 1998	Textiles — Hospital blankets, woollen, dyed — Specification (third revision)
6.	IS 4605 : 1981	Crepe Bandage — Specification (Second Revision)
7.	IS 4717 : 2020	Medical Textiles — Zinc Oxide Self-Adhesive Plaster — Specification (Second Revision)
8.	IS 4738 : 2020	Medical Textiles — Bandage, Plaster of Paris — Specification (Third Revision)
9.	IS 4739 : 1986	Specification for zinc oxide elastic self-adhesive bandage (first revision)
10.	IS 5405 : 2019	Sanitary napkins — Specification (second revision)
11.	IS 6237 : 1971	Specification for handloom cotton cloth for plaster of Paris bandages and cut bandages
12.	IS 9751 : 1981	Specification for bandage, suspensory
13.	IS 10829 : 1993	X-Ray detectable gauze swabs and laparotomy sponges – Specification (first revision)
14.	IS 11046 : 1984	Specification for towel, operating
15.	IS 11163 : 1985	Medical Textiles — First Aid Dressings — Specification
16.	IS 12839 : 1989	Wool/polyamide blended flannel, hospital, grey - Specification
17.	IS 14274 : 1995	Bandage, T - Shaped, calico - Specification
18.	IS 14306 : 1995	Bandage, triangular, calico – Specification

SI. No.	IS No.	TITLE
19.	IS 14316 : 1995	Swabs, small, in bag of 50 - Specification
20.	IS 14944 : 2020	Surgical Dressings — Methods of Test (First Revision)
21.	IS 16111 : 2013	Elastic bandage
22.	IS 16288 : 2014	Medical textiles — Method for evaluation of the bacterial filtration efficiency of surgical face masks
23.	IS 16289 : 2014	Medical textiles — Surgical face masks — Specification
24.	IS 16290 : 2014	Medical textiles — Knitted viscose primary dressings — Specification
25.	IS 16291 : 2014	Medical textiles — Paraffin gauze dressings — Specification
26.	IS 16302 : 2020	Medical Textiles — Orthopedic Stockinet — Specification (First Revision)
27.	IS 16303 : 2014	Medical textiles — Cast padding for orthopaedic plaster — Specification
28.	IS 16466 : 2020	Medical Textiles — Povidone Iodine Ointment Based Knitted Dressing — Specification (First Revision)
29.	IS 16467 : 2016	Medical textiles — Graduated medical compression stockings — Specification
30.	IS 16468 : 2016	Medical textiles — Absorbent cotton (Sterile and non-sterile) — Specification
31.	IS 16469 : 2016	Medical textiles — Open weave bandages — Specification
32.	IS 16470 : 2016	Medical textiles — Elastic surgical adhesive tapes — Specification
33.	IS 16545 : 2016 ISO 16604 : 2004	Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage
34.	IS 16546 : 2016 ISO 16603 : 2004	Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood
35.	IS 16548 : 2016 ISO 22612 : 2005	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration

SI. No.	IS No.	TITLE
36.	IS 16549 : 2020 ISO 22610 : 2018	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (first revision)
37.	IS 16660 : 2017	Medical textiles — Nonwoven bandage rolls — Specification
38.	IS 16668 : 2017	Medical textiles — Salicylic acid adhesive plaster — Specification
39.	IS 16669 : 2017	Medical textiles — Elastic adhesive dressing — Specification
40.	IS 16670 : 2017	Medical textiles — Absorbent cotton ribbon gauze — Specification
41.	IS 16671 : 2020	Medical Textiles — Belladonna Adhesive Plaster — Specification (First Revision)
42.	IS 16946 : 2018	Medical textiles — Elasticated tubular bandages — Specification
43.	IS 16948 : 2018	Medical textile — Permeable nonwoven surgical adhesive tape — Specification
44.	IS 16949 : 2018	Medical textiles — Adhesive extension plaster - Specification
45.	IS 16950 : 2018	Medical textiles — X - Ray detectable absorbent cotton gauze — Specification
46.	IS 17243 : 2019	Medical textiles — Test methods for compresses for wound management and surgical procedures
47.	IS 17333 : Part 1 : 2020	Textiles — Determination of antifungal activity of textile products Part 1 Luminescence method
48.	IS 17333 : Part 2 : 2020	Textiles — Determination of antifungal activity of textile products Part 2 Plate count method
49.	IS 17334 : 2019	Medical textiles—Surgical gowns and surgical drapes — Specification
50.	IS 17347 : 2020	Textiles – Determination of antiviral activity of textile products
51.	IS 17348 : 2020	Medical textiles – Adhesive incise drape – Specification
52.	IS 17349 : 2020	Medical textiles – Shoe covers – Specification
53.	IS 17350 : 2020	Medical textiles – Abdominal binder – Specification
54.	IS 17351 : 2020	Medical textiles – Dressing, shell compressed – Specification
55.	IS 17352 : 2020	Medical textiles – Foam dressing – Specification
56.	IS 17353 : 2020	Medical textiles – Pressure garment – Specification
57.	IS 17354 : 2020	Medical textiles – Dental bib/Napkins – Specification
58.	IS 17359 : 2020	Medical textiles – Anti-embolic stocking for Post op use upto thigh medium – Specification
59.	IS 17423 : 2020	Medical Textiles — Bio-Protective Coveralls — Specification (First Revision)
60.	IS 17506 : 2020	Medical Textiles — Hydrocolloid Dressing — Specification
61.	IS 17507 : 2020	Medical Textiles —Cellulose Wading — Specification
62.	IS 17508 : 2020	Disposable Adult Incontinence Diaper —Specification

SI. No.	IS No.	TITLE
63.	IS 17509 : 2021	Disposable Baby Diaper —Specification
64.	IS 17514 : 2021	Reusable Sanitary Pad/Sanitary Napkin/ Period panties —Specification
65.	IS 17528 : 2021	Medical Textiles — Chlorhexidine Gauze Dressing— Specification
66.	IS 17628 : 2021	Medical Textiles —Eye Pad —Specification
67.	IS 17629 : 2021	Medical Textiles —Caps —Specification
68.	IS 17630 : 2021	Medical Textiles— Bedsheet and Pillow Cover — Specification
69.	IS 17787 : 2021	Medical Textiles — Nonwoven Wipes — Specification
70.	IS 17788 : 2021	Medical Textiles — Nonwoven Fabric for Wipes — Specification
71.	IS/ISO 20645 : 2004 ISO 20645 : 2004	Textile fabrics — Determination of antibacterial activity — Agar diffusing plate test
72.	IS/ISO 20743 : 2013 ISO 20743 : 2013	Textiles — Determination of antibacterial activity of textile products
73	IS 17786 : 2022	Medical Textiles — Underpad — Specification (Under publication)